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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,812	05/08/2007	Hiroshi Kanai	40596	1931
53054 7590 09/30/2009 PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108				
EXAMINER FONTENOT, NIGEL RAI				
ART UNIT 3768		PAPER NUMBER		
NOTIFICATION DATE 09/30/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patdocket@peame.com
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Office Action Summary

Application No.

10/581,812

Applicant(s)

KANAI ET AL.

Examiner

NIGEL FONTENOT

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This action is responsive to the Arguments/Amendments filed August 13, 2009.

Claims 5-8 and 11-12 have been amended. Claims 1-12 are still pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-12 rejected under 35 U.S.C. 103(a) as being unpatentable over Caro et al. (US 5830131).

2. Addressing claims 1-12, Caro discloses an ultrasonic diagnostic method and apparatus for diagnosing vascular endothelial function by using an ultrasonic diagnostic apparatus (see col. 3 lines 14-40), comprising a transmitter/receiver for transmitting and receiving ultrasonic waves (see col. 22 lines 22-45), a phase detector for detecting a phase of the received ultrasonic echo (see fig. 5, col. 22 lines 22-45, and col. 23 lines

18-40; a phase is necessarily detected), and an arithmetic unit for calculating elastic modulus of vascular wall based on an ultrasonic echo obtained through phase detection (see col. 23 lines 18-40, the modulus is calculated based an echo that includes a phase), wherein said method comprising: a step (A) of transmitting ultrasonic waves into tissues of living body including vascular wall, and receiving an ultrasonic echo obtained when said ultrasonic waves is reflected and scattered by said vascular wall (see col. 22 lines 22-45); a step (B) of detecting a phase of said ultrasonic echo (see col. 22 lines 22-45; a phase is necessarily detected); and of determining elastic modulus of said vascular wall from a thickness change and a blood pressure value (see col. 23 lines 18-40; the tunica intima and tunica media are included in the vascular wall).

3. Caro doesn't explicitly disclose obtaining positional displacement of a plurality of positions within said vascular wall from a phase detection signal determined by said phase detector, obtaining thickness change between two arbitrary positions among said plurality of positions from a difference of positional displacement of said two positions. However, Caro discloses a piezoelectric sensor that senses arterial wall displacement and position (see col. 7 lines 9-17), discloses that the phase of the waveform corresponds to the blood pressure for many frequencies and is predictable based on this relationship (see col. 10 lines 42-62), and that the thickness of a vessel, modulus, or the vessel radius can change over time. Therefore, it would have been obvious to one of ordinary skill in the art to obtain positional displacement of a plurality of positions within said vascular wall from a phase detection signal determined by said phase detector, obtaining thickness change between two arbitrary positions among said

plurality of positions from a difference of positional displacement of said two positions since different parts of the vessel can have different properties as stated above. It would have further been obvious to store changes over time of elastic modulus of said vascular wall when avascularizing artery and then avascularization is stopped or display changes over time of elastic modulus of said vascular wall when avascularizing artery and then avascularization is stopped since Caro discloses that the thickness of a vessel, modulus, or the vessel radius can change over time including when blood is flowing through it and there is need to optimize treatments based on these parameters (see col. 23 lines 18-40).

Response to Arguments

4. Applicant's arguments filed August 13, 2009 have been fully considered but they are not persuasive. Claim 1 recites "an arithmetic unit for obtaining thickness change between two arbitrary positions among a plurality of positions with said vascular wall." Caro discloses a piezoelectric sensor that senses arterial wall displacement and position (see col. 7 lines 9-17), discloses that the phase of the waveform corresponds to the blood pressure for many frequencies and is predictable based on this relationship (see col. 10 lines 42-62), and that the thickness of a vessel, modulus, or the vessel radius can change over time. Caro monitors the patient over time for many parameters including blood pressure. Caro discloses mathematical relationships between wall thickness, modulus, pressure, phase, as well as other parameters and measurements. Caro discloses in col. 17 lines 37-49 that: "Subsequent to the initial determination of the

pressure-velocity relationship described above, it is desirable to periodically determine whether that relationship is still applicable. The relationship may become less applicable with time because of physiological changes in the patient due to endogenous or exogenous chemicals in the body that can affect the arterial muscular tone and, thus, the velocity of propagation of the exciter waveform. Even in the absence of changes in the patient, imperfect determination of the relationship due to measurement errors may lead to the need to check or redetermine the relationship periodically during a monitoring procedure." Therefore, it would have been obvious to one of ordinary skill in the art to obtain positional displacement of a plurality of positions within said vascular wall from a phase detection signal determined by said phase detector, obtaining thickness change between two arbitrary positions among said plurality of positions from a difference of positional displacement of said two positions since different parts of the vessel can have different properties as stated above. It would have further been obvious to store changes over time of elastic modulus of said vascular wall when avascularizing artery and then avascularization is stopped or display changes over time of elastic modulus of said vascular wall when avascularizing artery and then avascularization is stopped since Caro discloses that the thickness of a vessel, modulus, or the vessel radius can change over time including when blood is flowing through it and there is need to optimize treatments based on these parameters (see col. 23 lines 18-40).

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIGEL FONTENOT whose telephone number is (571)270-7032. The examiner can normally be reached on Monday-Friday (7:00a-4:00p).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. F./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768